

## REMARKS

### The Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claim 11, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the rejection indicates that the phrase “Alzheimer’s type” is relative and does not ascertain the scope of the phrase. Additionally, the rejection indicates that the metes and bounds of the phrase “medium chain triglyceride prodrug” appears ambiguous.

The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area which applicants regard as their invention with a *reasonable* degree of precision and particularity. Applicant believes the claim is clear as written; however, solely in the interest of expediting prosecution, the phrase “Alzheimer’s type” has been deleted from claim 11. Additionally, the phrase “medium chain triglyceride prodrug” has been amended to recite “prodrug of a medium chain triglyceride.” Applicant believes that this phrasing clarifies that the prodrug is a prodrug that can be metabolically converted to MCT by a recipient host (see specification, page 12.)

It is believed that the amendments are sufficient to overcome the rejection under 35 U.S.C. § 112, second paragraph. Reconsideration is respectfully requested.

### The Rejection under 35 U.S.C. § 102(b)

The Examiner has rejected Claim 11 under 35 U.S.C. § 102(b) as being anticipated by JP 06-287138. The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention.

*Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984); *Alco Standard Corp. v. Tennessee Valley Auth.*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). “There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *Scripps Clinic v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991) (citations omitted).

Applicant believes that claim 11, as amended, is not anticipated by the prior art relied upon by the Examiner. JP 06-287138 may teach a composition comprising MCTs, however, JP 06-287138 does not teach any form of prodrug of an MCT. That is, JP 06-287138 does not teach

a prodrug that can be metabolically converted to MCT by a recipient host. JP 06-287138 also does not teach administering an effective amount of such a prodrug to a patient. Because JP 06-287138 does not teach these limitations which are present in Claim 11, JP 06-287138 can not anticipate Claim 11. Reconsideration is respectfully requested.

The Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Schmidl, et al. U.S. Patent No. 5,504,072 in view of JP 06-287138. The Examiner bears the burden of establishing a *prima facie* case of obviousness (Section 103). In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is:

whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success . . . . Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure.

*In re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). The rejection states that Schmidl, et al. is used to show nutritional compositions comprising carbohydrate and a lipid component comprising MCT. The teachings of JP 06-287138 with regard to MCT are described above. There is no motivation to combine Schmidl, et al., and JP 06-287138. Schmidl teaches compositions which are nutritionally balanced and which provide complete nutritional support for critically ill patients (col. 3, lines 11-16). JP 06-287138 is concerned with another field altogether, which is the treatment of Alzheimer's disease. Schmidl, et al., utilizes a lipid component in the compositions, which may or may not include MCT and may also include long-chain fatty acids (column 4, lines 3-25). The purpose of the lipid component is to provide an energy source, and to provide essential fatty acids in the subject's diet (column 4, lines 6-8, and lines 32-40.) In contrast, the purpose of the lipid component is JP 06-287138, et al., is allegedly to increase the levels of aceytylcholine in the brain of Alzheimer's patients (Dialog Results (9/22/03) Agent for Prevention and/or therapeutics of Alzheimer's disease- contg. Triglyceride of 8-10 carbon fatty acids as active ingredient, Translation of Publication No. 06-287138, paragraph entitled USE/ADVNTAGE).

Given the wholly different purposes and compositions of Schmidl, et al., and JP 06-287138, one skilled in the art would not be motivated to combine the two. Additional reasons

that lead one to conclude that Schmidl, et al. and JP 06-287138 should not be combined have been previously presented. The rejection should be withdrawn on this basis alone.

Even if it were proper to combine Schmidl, et al. and JP 06-287138, the present invention would not result. JP 06-287138 does not teach a prodrug of an MCT (a prodrug that can be metabolically converted to MCT by a recipient host). JP 06-287138 also does not teach administering an effective amount of such a prodrug to a patient.

Schmidl, et al., does not teach a prodrug of an MCT (a prodrug that can be metabolically converted to MCT by a recipient host). Schmidl, et al., also does not teach administering an effective amount of such a prodrug to a patient.

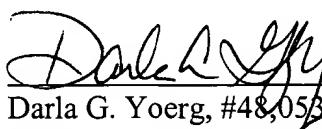
Neither reference teaches or suggests these limitations which are present in claim 11. The combination of these references, therefore, cannot render claim 11 obvious. Furthermore, applicant does not understand the relevance of the rejection's reference to "Alzheimer related loss of functional group" since this is not an element of Claim 11. Reconsideration is respectfully requested.

#### Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,



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